NOV 29 2010

VENUS CONCEPT

11/2

510(K) SUMMARY

Venus Freeze System

510(k) Number K 100586

Applicant's Name: Venus Concept Ltd.
62 HaHermesh Street
Karmiel, 21652, Israel
Tel: (972)3-644-6656
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Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Venus Freeze***

Preparation Date: February 28, 2010

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

The ***Venus Freeze*** is a noninvasive, non-ablative device consisting of:

- Main Unit (console)
- Touch Screen user interface
- RF Power module
- Controller unit
- Two treatment applicators:

  (1) Octipolar™ applicator – for large treatment areas, composed of 8 RF electrodes

  (2) Diamondpolar™ applicator – for small treatment areas, composed of 4 RF electrodes.

The Touch Screen user interface allows the selection of treatment parameters (time and power) by pressing on the treatment buttons and displays the current treatments settings.
The Controller Unit provides the operational and safety function of the system.
Treatment applicators transmit Bi-Polar RF energy in a method that creates an organized Bi-Polar RF energy matrix which produces homogeneous heating in the entire treatment area for maximum safety and efficacy, eliminating the need for pre/post cooling mechanisms.

The RF power module provides RF energy to the selected applicator, producing a 1MHz signal.

Intended Use Statement:

The ***Venus Freeze*** is a non-invasive device intended for use in Dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
EndyMed Imagine TC Skin Treatment System	**K083461**	Jul 24 2009
Lumenis Aluma	**K051214**	Oct 24 2005
Syneron Polaris	**K031671**	Dec 01 2003

Performance Standards

Venus Freeze complies with ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment.
In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following voluntary standards:

- ***EN 60601-1*** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- ***IEC 60601-1-2*** (Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests)

A detailed description appears in **Section 14**.

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Summary of Clinical performance data

The safety and efficacy of radiofrequency devices emitting energy with a frequency of 1000 KHz and power of 37 to 150 W is well established in scientific research and clinical studies. Multiple studies with these and similar systems have shown safety in dermatologic therapy and the devices were cleared by the FDA for therapy of wrinkles and rhytides.

Due to the comprehensive animal and clinical study performed in scientific research and published in the literature, and since the power and frequency of the ***Freeze*** are well within the previously cleared values, Venus-Concept believes that animal and clinical studies are not required to determine the safety and efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 29 2010

Venus Concept Ltd.
% Qsite
Mr. Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

Re: K100586
Trade/Device Name: Venus Freeze
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 27, 2010
Received: November 16, 2010

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 100586

Device Name: *Venus Freeze*

Indications for Use: The *Venus Freeze* is a non-invasive device intended for use in Dermatologic and general surgical procedures for the non-invasive treatment of mild to moderate facial wrinkles and rhytides.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

Mark Pople for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100586